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David A. Neumann, Ph.D.
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Draft Regulations on Research Waiver Applications for C-PORT II

Dear Dr. Neumann:

Thank you for the opportunity to review and comment on the draft regulations on Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery ["C-PORT II"]. Southern Maryland Hospital Center ("SMHC") has the following comments:

In general, SMHC believes the draft regulations are well conceived. However, SMHC has some concerns or questions about some provisions.

First, there is some potential conflict between the methodological needs of the research study for a large enough number of patients to reach statistically valid conclusions, on the one hand, and the Commission's intention to restrict the number of waivers issued to no more than six hospitals, on the other hand—especially if some of the six hospitals will be rural hospitals with a relatively small number of non-primary PCI patients. One way to balance these concerns would be to include the hospital's likely volume of non-primary PCI patients as an "appropriate factor" to consider in determining whether to grant a waiver under .04A(3). This would not duplicate the requirement that an applicant document that it will have at least 200 PCI procedures (both primary and non-primary) annually, since that requirement is a threshold test for approval while the criteria in .04A(3) are intended to allow comparisons between different applicants.

Second, SMHC is uncertain as to the meaning of .04A(2)(d), which states that an applicant must "commit to meet and maintain a patient follow-up rate of 98% for patients

enrolled in the C-PORT study." How long must this follow-up rate be maintained? (Six weeks? Six months? Six years?) If a hospital makes every reasonable effort to contact a patient for follow-up but is unable to contact the patient, is the patient counted in computing the follow-up rate? In practice, SMHC's experience in C-PORT I has been that at least ten percent of the patients are lost to follow-up because they cannot be contacted, despite reasonable efforts to do so. If the standard means that that no more than two percent of the patients can be lost to follow-up, it will be difficult or impossible to meet.

Finally, the proposed standard at .06A(3) would require that a hospital "immediately relinquish its waiver" if it "fails to notify the Commission within 48 hours of death, myocardial infarction, or stroke experienced by a patient participating in the C-PORT study." This seems unnecessarily draconian, particularly in view of the fact that the staff person responsible for reporting such events may not work seven days a week, so that an event occurring on a Friday evening would have to be reported by the following Sunday evening even if the staff person were not at the hospital on Saturday and Sunday. Is there truly an urgent need for the Commission to have this information within 48 hours? Will Commission staff be available seven days a week to receive the reports? What urgent actions would the Commission take in response to the report? We suggest that the standard be changed to require reporting within one week of the event.

Very truly yours,

Richard G. McAlee

cc: Michael Chiaramonte
Roy Leiboff, M.D.
Carole Clark, R.N.